

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: YGUERABIDE et al.

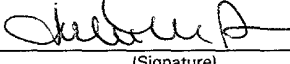
Title: ANALYTE ASSAY USING
PARTICULATE LABELS

Appl. No.: Unassigned

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PRELIMINARY AMENDMENT

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Sir:

Please amend the application as follows:

In the Specification:

Delete the first paragraph on Page 1, and insert the following paragraph:

This application is a divisional of Yguerabide et al., U.S. Application 08/953,713, filed October 17, 1997, which is a continuation-in-part of Yguerabide et al., U.S. Application 08/844,217, filed April 18, 1997, now U.S. Patent 6,214,560, which claims the benefit of Yguerabide et al., U.S. Provisional Application 60/016,383, filed April 25, 1996, all of which are incorporated herein by reference in their entireties, including drawings.

In the Claims:

Kindly cancel claims 1-48 and insert the following new claims.

- 1 49. (New) An apparatus for analysis of a sample on a solid phase surface,
2 comprising:
3 a light source oriented such that non-evanescent wave light is delivered to
4 said sample, and
5 a scattered light detector located such, when said solid phase surface is
6 present in said apparatus, said detector is on the opposite side of said solid phase
7 surface from the side from which said light is directed to said sample,
8 wherein said apparatus is configured such that light scattering particles
9 associated with said sample can be illuminated by said light under conditions which
10 produce scattered light from said particles and said scattered light can be detected
11 by a human eye with less than 500 times magnification and without electronic
12 amplification.
13
14 50. (New) The apparatus of claim 49, wherein a sample device comprises said
15 solid phase surface and said detector is essentially perpendicular to said solid phase
16 surface when said device is present in said apparatus.
17
18 51. (New) The apparatus of claim 49, wherein said apparatus is configured to
19 accept a sample device comprising said solid phase surface and said device is
20 selected from the group consisting of an array slide, an array chip, and an array
21 plate.
22
23 52. (New) The apparatus of claim 49, further comprising a sample device
24 comprising said solid phase surface.
25
26 53. (New) The apparatus of claim 52, wherein said sample device is selected from
27 the group consisting of an array slide, an array chip, and an array plate.

28

29 54. (New) The apparatus of claim 52, wherein said sample device is a microtiter
30 plate or other well-containing device.

31

32 55. (New) The apparatus of claim 53, wherein said solid phase surface is covered
33 by a medium, thereby increasing the refractive index of the medium surrounding said
34 light scattering particles.

35

36 56. (New) The apparatus of claim 51, further comprising a light guide for the
37 illuminating light.

38

39 57. (New) The apparatus of claim 56, wherein said light guide is a prism, optical
40 fiber, or optical fiber bundle.

41

42 58. (New) The apparatus of claim 49, further comprising one or more lenses
43 through which illuminating light passes, for collecting or focusing or both said
44 illuminating light.

45

46 59. (New) The apparatus of claim 49, further comprising a collection lens to collect
47 said scattered light for directing to said scattered light detector.

48

49 60. (New) The apparatus of claim 49, further comprising one or more lenses to
50 provide a focused image of said sample.

51

52 61. (New) The apparatus of claim 49, further comprising at least one optical filter,
53 arranged such that illuminating light, or scattered light, or both will pass through at
54 least one said optical filter.

55

56 62. (New) The apparatus of claim 61, wherein said optical filter is selected from
57 the group consisting of a narrow band pass filter, a cutoff filter, and a polarizer.

58

59 63. (New) The apparatus of claim 49, further comprising an electronic detector for
60 detecting scattered light.

61

62 64. (New) The apparatus of claim 63, further comprising an image processor that
63 discriminates light scattering signals based on color or intensity or both.

64

65 65. (New) The apparatus of claim 49, wherein said light source is selected from
66 the group consisting of light emitting diode (LED), laser diode, discharge lamp, and
67 filament lamp.

68

69 66. (New) The apparatus of claim 49, further comprising a particle counter having
70 necessary computer software or firmware configured to detect said scattered light
71 and count the number of said light scattering particles in a selected area.

72

73 67. (New) The apparatus of claim 49, further comprising an integrated light
74 intensity detector having necessary computer software or firmware configured to
75 detect said scattered light.

76

77 68. (New) The apparatus of claim 49, further comprising an integrated light
78 intensity detector and a particle counter, including necessary computer software or
79 firmware configured to detect said scattered light.

80

81 69. (New) The apparatus of claim 49, further comprising a photodetector selected
82 from the group consisting of a still camera, a video camera, and a CCD device,
83 configured to detect said scattered light.

84

85 70. (New) The apparatus of claim 49, wherein said apparatus is configured to
86 allow assay of a microarray.

87

88 71. (New) The apparatus of claim 70, wherein each separate area of said
89 microarray has a dimension between ten square microns and one square millimeter.
90

91 72. (New) The apparatus of claim 70, wherein each separate area of said
92 microarray has a dimension greater than one square millimeter.
93

94 73. (New) The apparatus of claim 71, wherein said apparatus detects the number
95 of particles in each of said separate areas.
96

97 74. (New) The apparatus of claim 72, wherein said apparatus detects the number
98 of particles in each of said separate areas.
99

100 75. (New) The apparatus of claim 71, wherein said apparatus is configured to
101 detect the light intensity in each of said separate areas.
102

103 76. (New) The apparatus of claim 72, wherein said apparatus is configured to
104 detect the light intensity in each of said separate areas.
105

106 77. (New) The apparatus of claim 49, wherein said apparatus is configured to
107 detect and distinguish light scattered from a plurality of different particle types.
108

109 78. (New) The apparatus of claim 77, wherein said apparatus distinguishes
110 different particles by color.
111

112 79. (New) The apparatus of claim 77, wherein said apparatus distinguishes
113 different particles by intensity.
114

115 80. (New) The apparatus of claim 77, wherein said apparatus distinguishes
116 different particles by peak light scattering wavelength.
117

118 81. (New) The apparatus of claim 78, wherein said apparatus comprises a plurality
119 of different bandpass filters to provide separate detection of light scattered from
120 different particle types.

121
122
123 82. (New) An apparatus for analysis of a sample on a solid phase surface,
124 comprising:

125 a light source oriented such that non-evanescent wave light is delivered to
126 said sample after passing through said surface when said solid phase surface is
127 present in said apparatus, wherein in passing through said solid phase surface said
128 light passes from a medium of higher refractive index into a medium of lower
129 refractive index, whereby a critical angle is defined, and

130 a scattered light detector located such that said detector is on the same side
131 of said solid phase surface as said light source when said solid phase surface is
132 present in said apparatus and said detector and said light source are both closer to
133 the perpendicular from said solid phase surface than said critical angle,

134 wherein said apparatus is configured such that light scattering particles
135 associated with said sample can be illuminated by said light under conditions which
136 produce scattered light from said particles and said scattered light can be detected
137 by a human eye with less than 500 times magnification and without electronic
138 amplification.

139
140 83. (New) The apparatus of claim 82, wherein a sample device comprises said
141 solid phase surface and said detector is essentially perpendicular to said solid phase
142 surface when said device is present in said apparatus.

143
144 84. (New) The apparatus of claim 82, wherein said apparatus is configured to
145 accept a sample device comprising said solid phase surface and said device is
146 selected from the group consisting of an array slide, an array chip, and an array
147 plate.

148

149 85. (New) The apparatus of claim 82, further comprising a sample device
150 comprising said solid phase surface.

151

152 86. (New) The apparatus of claim 85, wherein said sample device is selected from
153 the group consisting of an array slide, an array chip, and an array plate.

154

155 87. (New) The apparatus of claim 85, wherein said sample device is a microtiter
156 plate or other well-containing device.

157

158 88. (New) The apparatus of claim 86, wherein said solid phase surface is covered
159 by a medium, thereby increasing the refractive index of the medium surrounding said
160 light scattering particles.

161

162 89. (New) The apparatus of claim 84, further comprising a light guide for the
163 illuminating light.

164

165 90. (New) The apparatus of claim 89, wherein said light guide is a prism, optical
166 fiber, or optical fiber bundle.

167

168 91. (New) The apparatus of claim 82, further comprising one or more lenses
169 through which illuminating light passes, for collecting or focusing or both said
170 illuminating light.

171

172 92. (New) The apparatus of claim 82, further comprising a collection lens to collect
173 said scattered light for directing to said scattered light detector.

174

175 93. (New) The apparatus of claim 82, further comprising one or more lenses to
176 provide a focused image of said sample.

177

178 94. (New) The apparatus of claim 82, further comprising at least one optical filter,
179 arranged such that illuminating light, or scattered light, or both will pass through at
180 least one said optical filter.

181

182 95. (New) The apparatus of claim 94, wherein said optical filter is selected from
183 the group consisting of a narrow band pass filter, a cutoff filter, and a polarizer.

184

185 96. (New) The apparatus of claim 82, further comprising an electronic detector for
186 detecting scattered light.

187

188 97. (New) The apparatus of claim 96, further comprising an image processor that
189 discriminates light scattering signals based on color or intensity or both.

190

191 98. (New) The apparatus of claim 82, wherein said light source is selected from
192 the group consisting of light emitting diode (LED), laser diode, discharge lamp, and
193 filament lamp.

194

195 99. (New) The apparatus of claim 82, further comprising a particle counter having
196 necessary computer software or firmware configured to detect said scattered light
197 and count the number of said light scattering particles in a selected area.

198

199 100. (New) The apparatus of claim 82, further comprising an integrated light
200 intensity detector having necessary computer software or firmware configured to
201 detect said scattered light.

202

203 101. (New) The apparatus of claim 82, further comprising an integrated light
204 intensity detector and a particle counter, including necessary computer software or
205 firmware configured to detect said scattered light.

206

- 207 102. (New) The apparatus of claim 82, further comprising a photodetector
208 selected from the group consisting of a still camera, a video camera, and a CCD
209 device, configured to detect said scattered light.
210
- 211 103. (New) The apparatus of claim 82, wherein said apparatus is configured to
212 allow assay of a microarray.
213
- 214 104. (New) The apparatus of claim 103, wherein each separate area of said
215 microarray has a dimension between ten square microns and one square millimeter.
216
- 217 105. (New) The apparatus of claim 103, wherein each separate area of said
218 microarray has a dimension greater than one square millimeter.
219
- 220 106. (New) The apparatus of claim 104, wherein said apparatus detects the
221 number of particles in each of said separate areas.
222
- 223 107. (New) The apparatus of claim 105, wherein said apparatus detects the
224 number of particles in each of said separate areas.
225
- 226 108. (New) The apparatus of claim 104, wherein said apparatus is configured to
227 detect the light intensity in each of said separate areas.
228
- 229 109. (New) The apparatus of claim 105, wherein said apparatus is configured to
230 detect the light intensity in each of said separate areas.
231
- 232 110. (New) The apparatus of claim 82, wherein said apparatus is configured to
233 detect and distinguish light scattered from a plurality of different particle types.
234
- 235 111. (New) The apparatus of claim 110, wherein said apparatus distinguishes
236 different particles by color.

237

238 112. (New) The apparatus of claim 110, wherein said apparatus distinguishes
239 different particles by intensity.

240

241 113. (New) The apparatus of claim 110, wherein said apparatus distinguishes
242 different particles by peak light scattering wavelength.

243

244 114. (New) The apparatus of claim 111, wherein said apparatus comprises a
245 plurality of different bandpass filters to provide separate detection of light scattered
246 from different particle types.

247

248

249 115. (New) An apparatus for analysis of a sample on a solid phase surface,
250 comprising:

251 a light source angled such that light is delivered to said sample without first
252 passing through said solid phase surface when said solid phase surface is present in
253 said apparatus, and

254 a scattered light detector located such that said detector is on the same side
255 of said solid phase surface as said light source when said solid phase surface is
256 present in said apparatus,

257 wherein said apparatus is configured such that light scattering particles
258 associated with said sample can be illuminated by said light under conditions which
259 produce scattered light from said particles and said scattered light can be detected
260 by a human eye with less than 500 times magnification and without electronic
261 amplification.

262

263 116. (New) The apparatus of claim 115, wherein a sample device comprises said
264 solid phase surface and said detector is essentially perpendicular to said solid phase
265 surface when said device is present in said apparatus.

266

267 117. (New) The apparatus of claim 115, wherein said apparatus is configured to
268 accept a sample-bearing device selected from a slide and an array chip, wherein said
269 slide or array chip comprises said solid phase surface.

270

271 118. (New) The apparatus of claim 115, further comprising a sample device
272 comprising said solid phase surface.

273

274 119. (New) The apparatus of claim 118, wherein said sample device is selected
275 from the group consisting of an array slide, an array chip, and an array plate.

276

277 120. (New) The apparatus of claim 118, wherein said sample device is a microtiter
278 plate or other well-containing device.

279

280 121. (New) The apparatus of claim 119, wherein said solid phase surface is
281 covered by a medium thereby increasing the refractive index of the medium
282 surrounding said light scattering particles.

283

284 122. (New) The apparatus of claim 117, further comprising a light guide for the
285 illuminating light.

286

287 123. (New) The apparatus of claim 122, wherein said light guide is a prism, optical
288 fiber, or optical fiber bundle.

289

290 124. (New) The apparatus of claim 115, further comprising one or more lenses
291 through which illuminating light passes, for collecting or focusing or both said
292 illuminating light.

293

294 125. (New) The apparatus of claim 115, further comprising a collection lens to
295 collect said scattered light for directing to said scattered light detector.

296

297 126. (New) The apparatus of claim 115, further comprising one or more lenses to
298 provide a focused image of said sample.

299

300 127. (New) The apparatus of claim 115, further comprising at least one optical
301 filter, arranged such that illuminating light, or scattered light, or both will pass
302 through at least one said optical filter.

303

304 128. (New) The apparatus of claim 127, wherein said optical filter is selected from
305 the group consisting of a narrow band pass filter, a cutoff filter, and a polarizer.

306

307 129. (New) The apparatus of claim 115, further comprising an electronic detector
308 for detecting scattered light.

309

310 130. (New) The apparatus of claim 129, further comprising an image processor
311 that discriminates light scattering signals based on color or intensity or both.

312

313 131. (New) The apparatus of claim 115, wherein said light source is selected from
314 the group consisting of light emitting diode (LED), laser diode, discharge lamp, and
315 filament lamp.

316

317 132. (New) The apparatus of claim 115, further comprising a particle counter
318 having necessary computer software or firmware configured to detect said scattered
319 light and count the number of said light scattering particles in a selected area.

320

321 133. (New) The apparatus of claim 115, further comprising an integrated light
322 intensity detector having necessary computer software or firmware configured to
323 detect said scattered light.

324

325 134. (New) The apparatus of claim 115, further comprising an integrated light
326 intensity detector and a particle counter, including necessary computer software or
327 firmware configured to detect said scattered light.

328

329 135. (New) The apparatus of claim 115, further comprising a photodetector
330 selected from the group consisting of a still camera, a video camera, and a CCD
331 device, configured to detect said scattered light.

332

333 136. (New) The apparatus of claim 115, wherein said apparatus is configured to
334 allow assay of a microarray.

335

336 137. (New) The apparatus of claim 136, wherein each separate area of said
337 microarray has a dimension between ten square microns and one square millimeter.

338

339 138. (New) The apparatus of claim 136, wherein each separate area of said
340 microarray has a dimension greater than one square millimeter.

341

342 139. (New) The apparatus of claim 137, wherein said apparatus detects the
343 number of particles in each of said separate areas.

344

345 140. (New) The apparatus of claim 138, wherein said apparatus detects the
346 number of particles in each of said separate areas.

347

348 141. (New) The apparatus of claim 137, wherein said apparatus is configured to
349 detect the light intensity in each of said separate areas.

350

351 142. (New) The apparatus of claim 138, wherein said apparatus is configured to
352 detect the light intensity in each of said separate areas.

353

354 143. (New) The apparatus of claim 115, wherein said apparatus is configured to
355 detect and distinguish light scattered from a plurality of different particle types.

356

357 144. (New) The apparatus of claim 143, wherein said apparatus distinguishes
358 different particles by color.

359

360 145. (New) The apparatus of claim 143, wherein said apparatus distinguishes
361 different particles by intensity.

362

363 146. (New) The apparatus of claim 143, wherein said apparatus distinguishes
364 different particles by peak light scattering wavelength.

365

366 147. (New) The apparatus of claim 144, wherein said apparatus comprises a
367 plurality of different bandpass filters to provide separate detection of light scattered
368 from different particle types.

369

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REMARKS

Support for the preceding new claims is provided in the original claims, in the claims of the related provisional application, and in the specification. Thus, no new matter is presented.

Applicant believes that the present application is now in condition for allowance. Favorable consideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 16 August 2001

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